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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/849,109

05/18/2004

Kai-Tsung Teng

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MORRISON & FOERSTER LLP

755 PAGE MILL RD

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EXAMINER

NGUYEN, BAO THUY L

ART UNIT

PAPER NUMBER

1641

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/11/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary**Application No.**

10/849,109

Applicant(s)

TENG ET AL.

Examiner

Bao-Thuy L. Nguyen

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 3-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is vague and indefinite because it appears to use improper Markush language. The members of a Markush group must be functionally equivalent alternatives. In the instant case, it does not appear that nitrocellulose and glass fibers are functionally equivalent to liquid non-absorptive materials since nitrocellulose and glass fibers are generally considered absorbent materials.

Claim 3 is also vague because it is unclear if the liquid-flowing layer and the base member are made of the same material or if they are one and the same.

Claims 4-7 and 14-17 do not further limit claim 1 because they do not recite positive limitations to the assay device of claim 1. Claim 4, for example, recite limitation of the assay liquid sample which cannot be part of the device because assay samples are not normally collected until the time of the assay and even then, the final assay device product do not contain a liquid sample.

Claim 9 is vague and indefinite because it lacks antecedent support in the specification as originally filed. The specification at paragraph [0020] discloses only 2 "headrests" located at opposite ends of the sheet. The specification does not support the recitation of "a plurality" which could be more than 2.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson et al (US 5,726,064) in view of The Millipore Guide to Developing Test Strip.

Robinson discloses the invention substantially as claimed. Robinson teaches a waveguide comprising two plates of transparent material such as glass, separated by a narrow gap or cavity. One plate acts as an optical waveguide and carries an immobilized reagent appropriate to the test to be carried out. The other transparent plate can carry on its surface remote from the cavity a layer of light-absorbing or opaque material. The device can be used in a competitive or sandwich immunoassay. See column 8, line 64 through column 9, line 60. The transparent plates can be made of plastic material, quartz, similar or glass and are fixed together in parallel relationship,

less than 1 mm apart, preferably 0.1 mm, by means of bonding tracks of suitable adhesive. See column 20, lines 44-57. Robinson discloses glass microspheres of about 100 microns are placed in a pattern defining the long edges of one transparent plate, a sheet of glass is then placed over the waveguide, and a vacuum applied to the laminate. As a result, the plates are glued together and the microspheres defining a gap of 100 microns. See column 30, lines 10-25.

Robinson differs from the instant invention in failing to teach a base member.

The Millipore Guide discloses, in general, means for making test strip. Millipore teaches backing the test strip to provide added strength as well as other advantages. See page 13-16.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add a backing member such as taught by the Millipore Guide to the waveguide of Robinson for the advantages of an increase in tensile strength leading to easy of handling. A skilled artisan would have been motivated to applying a base, or backing member to provide a support structure to the device of Robinson because such backing is well known in the art.

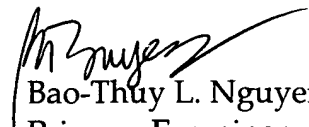
Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571)

272-0824. The examiner can normally be reached on Tuesday and Wednesday from 8:00 a.m. -4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641 1/6/07